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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/523,920

02/07/2005

Kazuhisa Mukai

MUKA12

1923

1444 7590 01/27/2010
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EXAMINER

BARNHART, LORA ELIZABETH

ART UNIT

PAPER NUMBER

1651

MAIL DATE

DELIVERY MODE

01/27/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/523,920	Applicant(s) MUKAI ET AL.	
	Examiner Lora E. Barnhart	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,6,7 and 21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,6,7 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendments

The examiner acknowledges applicant's reply mailed 11/20/09. Applicant has made no claim amendments in this reply. Claims 1, 2, 6, 7, and 21 as they are recited in the 1/7/07 reply remain pending and under consideration on their merits in the current application. References not included with this Office action can be found in a prior action.

Claim Rejections - 35 USC §§ 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 6, 7, and 21 remain rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Yamamoto et al. (1992, U.S. Patent 5,137,723).

Yamamoto teaches mixing maltose and L-ascorbic acid (L-AA) into a single solution, then adding rat intestine α -glucosidase (RIAGase) to the solution to yield 2-O-

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α -D-glucopyranosyl-L-ascorbic acid (AA-2G; Experiment 2; column 9, line 8, through column 12, line 44). Yamamoto teaches that AA-2G may also be made using a method in which L-AA is combined with cyclodextrin in a solution to which is added cyclomaltodextrin glucanotransferase (CGTase; Examples A-1 and A-2, column 13, line 20, through column 14, line 34). Yamamoto teaches that the yield of AA-2G is enhanced by contacting the reaction product of Example A-2 with glucoamylase (Example A-3; column 14, lines 35-62). Yamamoto teaches recovering AA-2G by purification on gel permeation and cation exchange columns, drying AA-2G with a vacuum, and isolating >99% pure crystals of AA-2G (column 9, lines 28-43 and column 13, line 32, though column 14, line 62, for example). Yamamoto teaches conducting their method using any of several α -glucosyl saccharides, including liquefied starch (column 3, line 62, through column 4, line 3).

The RIAGase and CGTase of Yamamoto are both " α -isomaltosyl glucosaccharide-forming enzymes" in accordance with claim 1 in that they combine L-AA with α -glucosyl saccharides to yield AA-2G.

The selection of the α -glucosyl saccharide to include in the reaction mixture of Yamamoto would have been a routine matter of optimization on the part of the artisan of ordinary skill, said artisan recognizing that Yamamoto teaches that the species recited in claim 1 are functional equivalents. A holding of obviousness over the cited claims is therefore clearly required.

Claim 1 describes the α -isomaltosyl glucosaccharide-forming enzyme used in the method as being "obtained from the genera *Arthrobacter*," which is a product-by-

process limitation. M.P.E.P. § 2113 reads, "Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps."

The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979)

The use of 35 U.S.C. §§ 102 and 103 rejections for product-by-process claims has been approved by the courts. "[T]he lack of physical description in a product-by-process claim makes determination of the patentability of the claim more difficult, since in spite of the fact that the claim may recite only process limitations, it is the patentability of the product claimed and not of the recited process steps which must be established. We are therefore of the opinion that when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972).

As discussed above, the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' α -isomaltosyl

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glucosaccharide-forming enzyme that is obtained from *Arthrobacter* differs, and if so to what extent, from the RIAGase discussed in Yamamoto. Yamamoto's RIAGase has α -isomaltosyl glucosaccharide-forming enzyme activity (i.e., it yields AA-2G from L-AA in the presence of an α -glucosyl saccharide). The cited art demonstrates a reasonable probability that the enzyme of Yamamoto is either identical or sufficiently similar to the claimed enzyme that whatever differences exist are not patentably significant.

Therefore, the burden of establishing novelty or unobviousness by objective evidence is shifted to applicants.

The mere fact that a characteristic of the enzyme of Yamamoto (e.g., the levels of AA-5G and AA-6G produced by its reaction with L-AA) was not disclosed by Yamamoto does not make methods employing that enzyme patentable. Applicant's enzyme possesses inherent characteristics which might not have been displayed in the tests used in Yamamoto; in other words, the fact that Yamamoto did not test the levels of AA-5G and AA-6G remaining in the reaction mixture does not indicate that the levels were higher than those claimed. Clear evidence that the method and enzyme of the cited prior art does not possess a critical characteristic that is possessed by the **claimed** method and enzyme (i.e., the levels of AA-5G and AA-6G **across the entire scope of the claims and elected species**) would advance prosecution and might permit allowance of claims to applicants' method of using the enzyme.

Applicants refer again to the Nishimoto declaration (submitted with the 7/8/09 reply) in support of patentability. In brief, the Nishimoto declaration compares the activity of Yamamoto's enzyme with that of the instant invention, both acting on

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PINEDEX #1, which is a commercially available composition containing maltodextrin, and finds that the instant enzyme provides an increased yield of AA-2G and decreased AA-5G and AA-6G contamination in the product. See, e.g., Table 1 at page 5 of the Nishimoto declaration. Applicants allege that the term “liquid starch” is narrower than the examiner has construed it. See reply, page 6. Applicant alleges that “liquefied starch,” the elected species, refers to hydrolyzed starch such as the maltodextrin in PINEDEX. See reply, pages 6-8. These arguments have been fully considered, but they do not overcome the rejection.

Applicant's reply regarding the definition of the term “liquefied starch” is persuasive, but the examiner maintains that the Nishimoto declaration does not address the entire scope of the elected species “liquefied starch.” The examiner draws applicant's attention to the fact that “maltodextrin,” the relevant contents of PINEDEX, is recited in claim 1 as a non-elected species; given the instant comments, it is not clear whether applicant intends to indicate that these are different species. In any case, the term “maltodextrin” refers to a family of starch hydrolysates that can be prepared from any starch source and can have different properties depending on the manner in which they are prepared. The Kearsley reference submitted by applicant indicates that hydrolysis can be carried out to yield products with varying dextrose equivalents (DE), and applicants stipulated to this fact in the 7/8/09 reply. See page 33, section 2.3.2, of Kearsley and page 12 of the 7/8/09 reply. Dokic et al. (1998, *Colloids and Surfaces A* 141: 435-440; reference U) teach that maltodextrins with different DE values have different physical properties, e.g. varying molecular weights, optical rotation, degrees of

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polymerization, and turbidity in aqueous solution. See Tables 1 and 2 at pages 436 and 437. Wang et al. (2000, *Starch* 52: 296-304; reference V) teach that maltodextrins prepared from different sources (for example, corn vs. potato) have different structures and different properties. See page 303, section 4. The art appears to have formed consensus that the properties of maltodextrins vary. The Nishimoto declaration addresses a single maltodextrin prepared from tapioca starch. Applicant has not established that any given maltodextrin would yield the same results. The Nishimoto declaration, given the teachings of Dokic and Wang as to variations in maltodextrin properties, does not address the entire scope of “liquefied starch.”

The examiner also notes that the claim is not commensurate in scope with the specification and the Nishimoto declaration with respect to the α -isomaltosyl glucosaccharide-forming enzyme. Claim 1 requires that the enzyme be obtained from the genus *Arthrobacter*, but the specification and Nishimoto declaration are confined to a discussion of the specific strain *Arthrobacter globiformis* A19. See page 18 of the specification. There is no evidence that all enzymes from all *Arthrobacter* species would yield the same results as the *A. globiformis* A19 strain in applicant’s method.

No claims are allowed. No claims are free of the art.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart whose telephone number is (571)272-1928. The examiner can normally be reached on Monday-Thursday, 9:00am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lora E Barnhart/

Primary Examiner, Art Unit 1651